

Clinical Study Experience

Dr. Susan Feyerabend

Clinical AMG - Studies as National Head of Investigators (Leitender Prüfarzt, LKP) since 2009

2009-2011

Extension study of Degarelix versus Goserelin in hormone-naive prostate cancer patients, phase III

2015- 2019

Randomized, double-blind study with enzalutamide in chemotherapy naive mCRPC patients treated with docetaxel who have progressed on enzalutamide alone, PRESIDE, phase IIIb, 9785-MA-1001, EudraCT No 2013-004711-50

2017

Randomized study of 2 doses of AQX-1125 targeting the SHIP1 pathway in subjects with Interstitial Cystitis / Bladder Pain syndrome followed by a 40-week extension period phase III, EudraCT No 2016-000906-12

2017- 2020

Extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study, phase II, EudraCT No 2016-001694-32

2017- 2020

Open Label, Randomized Study to Assess the Efficacy and Safety of Olaparib (Lynparza™) Versus Enzalutamide or Abiraterone Acetate in Men with Metastatic Castration-Resistant Prostate Cancer Who have Failed Prior Treatment with a New Hormonal Agent and Have Homologous Recombination Repair Gene Mutations, PROFOUND, phase III, D081DC00007, EudraCT No

2017-2019

Randomized, double-blind, placebo-controlled proof of concept study to investigate efficacy, safety, pharmacodynamics and pharmacokinetics of ASP6294 in the treatment of female subjects with bladder pain syndrome / interstitial cystitis, SERENITY, 6294-CL-0101, phase IIa, EudraCT No 2016-004138-12

2018 - 2020

Open-label study of Rucaparib in patients with locally advanced or metastatic urothelial carcinoma, ATLAS, CO-338-085, phase II, EudraCT No 2017-004166-10

2022-

A Phase III Double-Blind, Randomised, Placebo-Controlled Study Assessing the Efficacy and Safety of Capivasertib + Abiraterone Versus Placebo + Abiraterone as Treatment for Patients with De Novo Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Characterised by PTEN deficiency (CAPitello-281), (EudraCT 2020-000346-33)

Clinical AMG - Studies as Principal Investigator since 2009

Prostate Cancer

2009-2011

Treatment with Degarelix versus Goserelin in hormone-naive prostate cancer patients, phase III
EudraCT No 2008-005276-27

2010-2013

Firstlinetherapy with Docetaxel / Prednisone +/- OGX-011 in metastatic hormone refractory prostate cancer patients, SYNERGY, phase III, EudraCT No 2010-021011-16

2011-2013

TAK-700 / Prednisone versus placebo in chemo-naive metastatic hormone refractory prostate cancer patients, C21004, phase III, EudraCT No 2010-018661-35

2011-2013

Randomized double-blind study with TAK-700 / Prednisone in metastatic hormone refractory prostate cancer patients who have progressed after docetaxel chemotherapy, C21005, phase III, EudraCT No 2010-018662-23

2011-2013

Randomized double-blind study with Integrinantibody EMD in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase II, EMR 62242-006, EudraCT No 2010-021529-11

2011-2013

Randomized double-blind study with Tasquinimod in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, 10TASQ10, phase III, EudraCT No 2010-021870-12

2012- 2016

Secondlinechemotherapy Cabazitaxel 20 versus 25 mg/m² in patients having progressed after docetaxel treatment, PROSELICA, phase III, EudraCT No 2010-022163-35

2012-2017

Randomized double-blind study with RNaive versus placebo in metastasized, chemo-naive, hormone refractory prostate cancer patients, CV9104-004, phase IIb, EudraCT No 2011-006314-14

2013-2014

Cabozantinib versus Prednisone in metastatic hormonrefractory prostate cancer, COMET-1, XL194-307, phase III, EudraCT No 2012-001834-33

2013-2014

Enzalutamid versus Bicalutamid in metastatic hormonrefractory prostate cancer, TERRAIN, 9785-CL-0222, phase II, EudraCT No 2010-021868-15

2014-2017

Randomized double-blind study with Abiraterone in combination with LH-RH therapy in newly diagnosed high risk, hormone-naive prostate cancer patients, LATITUDE, 212082PCR3011, phase II, EudraCT No 2012-002940-26

2014-2017

Abiraterone with different steroid regimens for preventing symptoms associated with mineralocorticoide excess in asymptomatic, chemotherapy-naive and metastatic CRPC, 212082PCR2023, phase II, EudraCT No 2012-004331-23

2014-2015

Randomized double-blind study with Tasquinimod as maintenance therapy in metastatic prostate cancer patients without progress after firstline docetaxel containing chemotherapy, p8-55-58102-002, phase II, EudraCT No 2012-001038-32

2014-2017

Randomized double-blind study with PROSTVAC-V/F +/- GM-CSF in men with asymptomatic or mildly symptomatic metastatic, castrate-resistant prostate cancer, BNIT-PRV-301, phase III, EudraCT No 2010-021196-85

2014-2018

Randomized double-blind study with DCVAC/PCa in men with metastatic hormonrefractory prostate cancer eligible for 1st line chemotherapy, VIABLE, SP005, phase III, EudraCT No 2012-002814-38

2014-2019

Randomized double-blind study with ARN-509 in men with non-metastatic castration - resistant prostate cancer, SPARTAN, ARN-509-003, phase III, EudraCT No 2012-004322-24

2014-2017

Open label study with enzalutamide in patients with hormone-refractory prostate cancer having progressed on abiraterone therapy, 9785-CL-0410, phase IV, EudraCT No 2013-002271-17

2014- 2018

Randomized double-blind study with MDV-3100 in patients with non-metastatic, castrate-resistant prostate cancer, PROSPER, MDV3100-14, phase III, EudraCT No 2012-005665-12

2015-2018

Randomized cabazitaxel dose individualization and neutropenia prevention trial, CAINTA, phase II, EudraCT No 2013-005504-34

STUDIENPRAXIS UROLOGIE

DR. S. FEYERABEND · PROF. DR. T. TODENHÖFER

2015-2018

Continued enzalutamide in chemotherapy naive mHRPC patients treated with docetaxel / prednisone having progressed on enzalutamide alone, PRESIDE, 9785-MA-1001, phase IIIb, EudraCT No 2013-004711-50

2015-2017

Radium-223 alpha emitter agent in non-intervention safety study in mCRPC population for long-term evaluation, phase IV, REASSURE

2015-2020

Randomized double-blind study with ODM-201 in patients with non-metastatic, castrate-resistant prostate cancer, ARAMIS, 17712, phase III, EudraCT No 2015-002590-38

2015-2017

Single-arm, open-label, post marketing safety study to evaluate the risk of seizure among subjects with metastatic castration-resistant prostate cancer treated with enzalutamide who are at potential increased risk for seizure, UPWARD, 9785-CL-0403, phase IV, EudraCT No 2013-003022-92

2015-2016

Study to evaluate pharmacodynamic, pharmacokinetic and safety of Zoreline 10,8 mg subcutaneous Goserelin-implant in subjects with prostate cancer, phase III, EudraCT No 2013-000799-14

2015-2017

Randomized double-blind study with JNJ-56021927 versus placebo in combination with Abiraterone in metastatic HPRC in chemotherapy-naive men, ACIS, 56021927PCR3001, phase III, EudraCT No 2014-001718-25

2016-2019

Randomized double-blind study with JNJ-56021927 plus androgen deprivation therapy (ADT) versus ADT in subjects with low volume metastatic, hormone sensitive prostate cancer, TITAN, 56021927PCR3002, phase III, EudraCT No 2015-000735-32

2016-

Randomized double-blind study with JNJ-56021927 plus androgen deprivation therapy (ADT) versus ADT in subjects with high risk or locally advanced prostate cancer receiving primary radiation therapy, ATLAS, 56021927PCR3003, phase III, EudraCT No 2015-003007-38

2016-2018

Clinical efficacy of abiraterone acetate while sparing LHRH-therapy in patients with castration-resistant prostate cancer progressing after chemotherapy, SPARE, AP 67/11, phase II, EudraCT No 2012-005717-39

2016-2017

Comparator study in men expressing androgen receptor splice variant-7 mRNA (AR-V7) and metastatic castrate resistant prostate cancer, ARMOR3-SV, phase III, EudraCT 2014-005079-10

2016-2022

Pembrolizumab (MK-3475) in subjects with mCRPC previously treated with chemotherapy, KEYNOTE-199, MK-3475-199, phase II, EudraCT 2015-003644-40

2016-2019

European prospective non-interventional study to evaluate efficacy of enzalutamide in the treatment of patients with metastatic hormone-refractory prostate cancer, PREMISE, 9785-MA-1002, phase IV

2017-2020

Extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study, 9785-CL-0123, Phase II, EudraCT No 2016-001694-32

2017-2022

Randomized study of ODM-201 in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer, ARASENS, 17777, Phase III, EudraCT No 2015-002590-38

2017-2020

Randomized, open-label study of Cabazitaxel versus an androgen receptor (AR)-targeted agent (abiraterone or enzalutamide) in mCRPC patients previously treated with Docetaxel and who rapidly failed a prior AR-targeted agent, CARD, LPS14201, Phase IV, EudraCT No 2014-004676-29

2017-

Randomized double-blind, placebo-controlled study of enzalutamide in men with metastatic hormone-sensitive prostate cancer plus androgen deprivation therapy, ARCHES, CL-9785-0335, Phase III, EudraCT Nr. 2015-003869-28

2017-

Pembrolizumab (MK-3475) combination therapies in mCRPC, phase Ib/II, KEYNOTE-365, EudraCT No. 2016-002312-41

2017-2019

Open label, randomized study to assess the efficacy and safety of Olaparib (Lynparza) versus enzalutamide or Abiraterone Acetate in men with mCRPC who have failed prior treatment with a new hormonal agent and have homologous recombination repair gene mutations, phase III, PROfound, D081DC00007, EudraCT No.

2017-2018

Treatment with Abiraterone Acetate for metastasized hormone-refractory prostate cancer: early or late onset of therapy, TIME, phase IV

2017-2019

Correlation between common clinical outcome parameters, CTC-changes and ARV7-status (androgen receptor splice variant 7) in patients with mCRPC treated with first line abiraterone acetate, STAR-V7, EudraCT No. 2016-002735-16

2018-2020

Open-label study of Rucaparib in patients with metastatic castration-resistant prostate cancer associated with homologous recombination deficiency, TRITON2, CO-338-052, phase II, EudraCT No. 2016-003162-13

2018-2019

Randomized trial for patients with rapidly progressive mHRPC: abiraterone acetate, prednisolone, LHRH-agonist and denosumab versus abiraterone acetate, dexamethasone, LHRH-agonist and denosumab plus biomodulatory therapy including metronomic low-dose treosulfan plus pioglitazone, Moduprostate01 Study, EudraCT No. 2015-004221-14

2018-

Randomized, open-label study of rucaparib versus physician's choice of therapy for patients with metastatic castration-resistant prostate cancer associated with homologous recombination deficiency, TRITON3, CO-338-063, phase III, EudraCT No. 2016-003163-20

2018-2021

Randomized, placebo-controlled trial testing ipatasertib plus abiraterone plus prednisone relative to placebo plus abiraterone plus prednisone in patients with asymptomatic or mildly symptomatic, previously untreated, metastatic castrate-resistant prostate cancer, CO39303, phase III, EudraCT No. 2016-004429-17

2018-2019

Open-label, response rate study of talazoparib in men with DNA repair defects and metastatic castration-resistant prostate cancer who previously received taxane-based chemotherapy and progressed on at least 1 novel hormonal agent, TALAPRO-1, phase II, EudraCT No. 2016-002036-32

2019-

Randomized study of Abemaciclib + Abiraterone versus Abiraterone alone in metastatic castration-resistant prostate cancer, I3Y-MC-JPCM, phase II, EudraCT No.

2019-

A Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for Treatment of Participants With Metastatic Prostate Cancer (MAGNITUDE), Phase III, EudraCT No 2017-003364-12

2019-

Trial Evaluating the Safety of 2 Schedules of Cabazitaxel in Elderly Men With mCRPC Previously Treated With a Docetaxel (CABASTY). Phase III, EudraCT No 2016-001179-60

2019

Phase III, open-label, multi-center study to assess the pharmacodynamic (PD), pharmacokinetic (PK) and safety of Zoreline 10.8 mg goserelin subcutaneous implant (Novalon) in male subjects with prostate cancer EudraCT2015-001756-30-BG

2019-

A Randomised, Double-blind, Placebo-controlled, Multicentre Phase III Study of Olaparib Plus Abiraterone Relative to Placebo Plus Abiraterone as First-line Therapy in Men with Metastatic Castration-resistant Prostate Cancer, PROPEL, D081DC00001, EudraCT

2019-

Talazoparib + Enzalutamide vs. Enzalutamide Monotherapy in mCRPC (TALAPRO-2), Phase III, EudraCT 2017-003295-31

2019-2020

Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Metastatic Castration-resistant Prostate Cancer (mCRPC) (MK-7339-010/KEYLYNK-010) (KEYLYNK-010), EudraCT 2018-004118-16

2019-2020

Study of Pembrolizumab (MK-3475) Plus Docetaxel Versus Placebo Plus Docetaxel in Chemotherapy-naïve Metastatic Castration-resistant Prostate Cancer (mCRPC) (MK-3475-921/KEYNOTE-921), EudraCT 2018-004116-22

2019-2022

A multicenter Phase IIb trial to evaluate the efficacy and tolerability of ModraDoc006/r in subjects with metastatic Castration Resistant Prostate Cancer (mCRPC), suitable for treatment with a taxane, EudraCT 2019-000582-21

2020-

Randomized, open-label study of adjuvant Apalutamide or standard of care in subjects with high-risk, localized or locally advanced prostate cancer after radical prostatectomy, ADAM, phase II, EudraCT 2018-004329-10

2021-

A Phase 3, Randomized, Double-Blind Study of Nivolumab or Placebo in Combination mit Docetaxel in Men with Metastatic Castration Resistant Prostate Cancer (mCRPC), CheckMate 7DX, EudraCT 2019-002030-36

2021-

A Phase 3, Randomized, Open-Label, Controlled Study of Cabozantinib (XL184) in Combination With Atezolizumab vs Second Novel Hormonal Therapy (NHT) in Subjects With Metastatic Castration-Resistant Prostate Cancer, CONTACT, EudraCT 2020-000348-77

2021-

A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Niraparib in Combination With Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants With Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer, AMPLITUDE (mCSPC), EudraCT 2020-002209-25

2022-

A First-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of W_pro1 (BNT112) monotherapy and in combination with cemiplimab in patients with prostate cancer, Pro-Merit, RN5609C00, EudraCT 2018-004321-86

2022-

A Dose-Escalation and Expansion Study of the Safety and Pharmacokinetics of XL092 as Single-Agent and Combination Therapy in Subjects with Inoperable Locally Advanced or Metastatic Solid Tumors, XL092-001, EudraCT 2020-003569-21

2022-

A Phase 3, Randomized, Double-Blind, Study of TALAZOPARIB with ENZALUTAMIDE versus Placebo with Enzalutamide in men with DDR gene mutated mHSPC, TALAPRO-3, PF-06944076, EudraCT 2021-000248-23

2022-

A Phase III Double-Blind, Randomised, Placebo-Controlled Study Assessing the Efficacy and Safety of Capiivasertib + Abiraterone Versus Placebo + Abiraterone as Treatment for Patients with De Novo Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) Characterised by PTEN deficiency, CAPItello-281, EudraCT 2020-000346-33

2022-

An Open-Label, multicenter, single arm study to assess the efficacy and safety of triptorelin 6-month formulation administered subcutaneously in participants with locally advanced and/or metastatic prostate cancer previously treated and castrated with a GnRH analogue, D-FR-52014-245, phase III, EudraCT 2021-005719-29

2022-

A Phase III, Randomized, Double-Blind, Placebo Controlled Study of Abemaciclib in combination with Abiraterone plus Prednisone in Men with High-Risk Metastatic Hormone-Sensitive Prostate Cancer, I3Y-MC-JPEG, EudraCT 2022-500020-30-00

Painful Pelvis Syndrome

2012-2013

Randomized double-blind study with ASP3652 in women with painful pelvis syndrome / interstitial cystitis, phase II, EudraCT No 2011-004555-39

2017-

Randomized study of 2 doses of AQX-1125 targeting the SHIP1 pathway in subjects with Interstitial Cystitis / Bladder Pain syndrome followed by a 40-week extension period phase III, EudraCT No 2016-000906-12

2017-

Randomized, double-blind, placebo-controlled proof of concept study to investigate efficacy, safety, pharmacodynamics and pharmacokinetics of ASP6294 in the treatment of female subjects with

bladder pain syndrome / interstitial cystitis, SERENITY, 6294-CL-0101, phase IIa, EudraCT No 2016-004138-12

Non-muscle invasive Bladder Cancer

2015-

Randomized, intravesical Mistletoe Extract in Superficial Bladder Cancer: A Phase III Efficacy Study, TIM, EudraCT No 2013-003446-16

2018-

Randomized, open-label study of Durvalumab and Bacillus Calmette-Guerin (BCG) administered as combination therapy versus BCG alone in high-risk, BCG-naive non-muscle-invasive Bladder Cancer Patients, POTOMAC, phase III, EudraCT 2017-002979-26

Metastatic Muscle Invasive Bladder Cancer

2017- 2021

Single-agent multicenter study to evaluate the efficacy and safety of INCB054828 in subjects with metastatic or unresectable urothelial carcinoma harboring FGF/FGFR alterations, phase II, EudraCT No 2016-001321-14

2018 - 2020

Open-label study of Rucaparib in patients with locally advanced or metastatic urothelial carcinoma, ATLAS, CO-338-085, phase II, EudraCT No 2017-004166-10

2019-

A Study of Erdafitinib Compared With Vinflunine or Docetaxel or Pembrolizumab in Participants With Advanced Urothelial Cancer and Selected Fibroblast Growth Factor Receptor (FGFR) Gene Aberrations. Phase III, EudraCT No 2017-002932-18

2019-2022

A Single-Arm Study of Bempegaldesleukin (NKTR-214) Plus Nivolumab in Cisplatin Ineligible Patients Who Have Locally Advanced or Metastatic Urothelial Cancer (PIVOT-10), EudraCT 2018-003636-79

2022

A Phase III Randomized, Open-Label, Multicenter Study to Determine the Efficacy and Safety of Durvalumab in combination with Tremelimumab and Enfortumab Vedotin or Durvalumab in combination with Enfortumab Vedotin for perioperative Treatment in Patients Ineligible for Cisplatin or Who Refuse Cisplatin Undergoing Radical Cystectomy for Muscle Invasive Bladder Cancer, VOLGA, EudraCT 2020-005452-38

Advanced Renal Cancer

2017-

Double-blind, placebo-controlled trial of Pembrolizumab (MK-3475) as monotherapy in the adjuvant treatment of renal cell carcinoma post nephrectomy, KEYNOTE-564, phase III, EudraCT No 2016-004351-75

Clinical AMG - Studies as Subinvestigator since 2003

Prostate Cancer

2004 - 2005

Safety in patients with bone metastases from prostate cancer treated with zoledronic acid, phase III

2004 - 2005

Randomized double-blind study with IgG - Antibody MT201 in biochemically relapsed patients after prostatectomy, phase II

2004 - 2013

Zometa versus active surveillance in high risk prostate cancer patients in prophylaxis for the development of bone metastases, phase III, EudraCT No

2004 - 2008

Peptide vaccination in patients with biochemical relapse after prostatectomy, phase I/II, EudraCT No

2005 -2008

Evaluation of bone markers as diagnostic tool in the screening for bone metastases in high-risk patients, phase IV

2005 - 2007

Tolerability and efficacy of a daily dose versus per need of Vardenafil versus placebo in men after verve-preserving radical prostatectomy, phase II, EudraCT No 2006-002361-39

2006 - 2008

Randomized double-blind study with ZD6474 in combination with docetaxel / prednisone chemotherapy in hormone refractory, metastatic prostate cancer, phase III, EudraCT No 2005-003593-16

2006 - 2008

Combination therapy of Glivec, Ovastat, Arcoxia, Actos and Fortecortin in metastasized hormone refractory prostate cancer, phase II, EudraCT No 2006-00218-19

2007 - 2013

Randomized double-blind study with Denosumab prophylactic for prevention of development of bone metastases in hormone refractory prostate cancer, phase III

2007 - 2010

Denosumab versus Zometa in patients with bone metastases in hormone refractory prostate cancer, phase III, EudraCT No 2006-000341-19

2007 - 2008

STUDIENPRAXIS UROLOGIE

DR. S. FEYERABEND · PROF. DR. T. TODENHÖFER

DN101 versus placebo in combination with docetaxel / prednisone (ASCENT), phase III, EurdraCT Nr.

2008 - 2009

Randomized double-blind study with integrinantibody in combination with docetaxel / prednisone in metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2006-005766-39

2008 - 2010

Randomized double-blind study with docetaxel / prednisone in combination with Endothelin A receptor antagonist versus placebo in metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2007-003228-39

2008 - 2009

Randomized double-blind study with endothelin A receptor antagonist in hormone refractory prostate cancer patients with bone metastases, phase III, EurdraCT No 2007-003224-38

2008 - 2009

Sagopilone +/- L-Carnithin in firstline treatment of metastatic hormone refractory prostate cancer, phase II, EurdraCT No 2008-000879-26

2009 - 2010

Randomized double-blind study with suturent in metastatic hormone refractory prostate cancer having progressed after docetaxel treatment, phase II, EurdraCT No 2008-002158-40

2009 - 2010

RNA vaccination therapy in metastatic hormone refractory prostate cancer, phase I, EurdraCT No 2008-003967-37

2009 - 2010

Intermittent treatment with LH-RH antagonist Degarelix, phase III, EurdraCT No 2008-005276-27

2010 - 2012

Randomized double-blind study with MDV3100 in metastatic hormone refractory prostate cancer having progressed after docetaxel treatment, phase III, EurdraCT No 2009-013174-41

2010 - 2013

Docetaxel / Prednisone +/- OGX-011 in firstline chemotherapy in metastatic hormone refractory prostate cancer, phase III, EurdraCT No 2010-021011-16

2011-2013

Randomized double-blind study with TAK-700 / Prednisone in chemo-naive metastatic hormone refractory prostate cancer patients, phase III, EurdraCT No 2010-018661-35

2011-2013

Randomized double-blind study with TAK-700 / Prednisone metastatic hormone refractory prostate cancer patients who have progressed after docetaxel chemotherapy, phase III, EurdraCT No 2010-018662-23

2011-2013

Randomized double-blind study with integrinantibody EMD in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase II, EudraCT No 2010-021529-11

2011-2013

Randomized double-blind study with Tasquinimod in bone metastasized, chemo-naive, hormone refractory prostate cancer patients, phase III, EudraCT No 2010-021870-12

2011 - 2012

Docetaxel / Prednisone in combination with Lenalidomide versus placebo in firstline chemotherapy in hormone refractory prostate cancer, phase III, EudraCT No 2008-007969-23

2011 - 2013

MDV3100 in hormone refractory prostate cancer in chemo-naive hormone refractory prostate cancer, phase III, EudraCT No 2010-020821-41

2012-2013

Secondlinechemotherapy Cabazitaxel 20 versus 25 mg/m² in patients having progressed after docetaxel treatment, phase III, EudraCT No 2010-022163-35

2012 - 2013

Randomized double-blind study with RNActive versus placebo in chemo-naive hormone refractory prostate cancer, phase IIb, EudraCT No 2011-006314-14

2012 - 2013

Dose titrating study of Pasireotide in chemo-naive, metastasized hormone refractory prostate cancer, phase I, EudraCT No 2010-024399-25

2013-2014

Cabozantinib versus prednisone in metastatic hormonerefractory prostate cancer, phase III, EudraCT No 2012-001834-33

2013-2014

Abiraterone with different steroid regimens for preventing symptoms associated with mineralocorticoid excess in asymptomatic, chemotherapy-naive and metastatic CRPC, phase II, EudraCT No 2012-004331-23

2014-2016

An Open Label Randomised Trial of RNActive® Cancer Vaccine in High Risk and Intermediate Risk Patients With Prostate Cancer, phase II, EudraCT No 2013-004489-32

2014- 2017

Randomized double-blind study with Tasquinimod as maintenance therapy in metastatic prostate cancer patients without progress after firstline docetaxel containing chemotherapy, phase II, EudraCT No 2012-001038-32

2014 - 2017

Randomized double-blind study with PROSTVAC-V/F +/- GM-CSF in men with asymptomatic or mildly symptomatic metastatic, castrate-resistant prostate cancer, phase III, EudraCT No 2010-021196-85

2014 - 2019

Randomized double-blind study with DCVAC/PCa in men with metastatic hormonrefractory prostate cancer eligible for 1st line chemotherapy, phase III, EudraCT No 2012-002814-38

2014

Randomized double-blind study with ARN-509 in men with non-metastatic castration - resistant prostate cancer, phase III, EudraCT No 2012-004322-24

2014

Open label study with enzalutamide in patients with hormone-refractory prostate cancer having progressed on abiraterone therapy, phase IV, EudraCT No 2013-002271-17

2019 –

Study of Nivolumab Plus Ipilimumab, Ipilimumab or Cabazitaxel in Men With Metastatic Castration-Resistant Prostate Cancer (CheckMate 650), Phase II, EudraCT: 2016-001928-54

2020-

A Phase 2, Double-Blind, Placebo Controlled Study of RV001V in Men with Biochemical Failure following Curatively Intended Therapy For Localized Prostate Cancer, EudraCT-Nr. 2019-000951-14

2020-

Study of Pembrolizumab (MK-3475) Plus Olaparib Versus Abiraterone Acetate or Enzalutamide in Metastatic Castration-resistant Prostate Cancer (mCRPC) (MK-7339-010/KEYLYNK-010) (KEYLYNK-010), EudraCT 2018-004118-16

2020-

Study of Pembrolizumab (MK-3475) Plus Docetaxel Versus Placebo Plus Docetaxel in Chemotherapy-naïve Metastatic Castration-resistant Prostate Cancer (mCRPC) (MK-3475-921/KEYNOTE-921), EudraCT 2018-004116-22

Benigne Hyperplasia of the Prostate

2007 - 2008

Safety and efficacy of Lonidamine in patients with benigne prostate hyperplasia, phase II, EudraCT No 2005-001073-94

Urothelial Carcinoma

2004 - 2013

STUDIENPRAXIS UROLOGIE

DR. S. FEYERABEND · PROF. DR. T. TÖDENHÖFER

Gemcitabine plus Cisplatin in combination with or without Gefitinib sequentiell or concomitant in metastatic urothelial cancer, phase II, EudraCT No

2004 - 2006

Secondline Chemotherapie in Cisplatin pretreated patients with Gemcitabine / Paclitaxel, phase II

2004 - 2005

MVAC in organerestricted urothelial cancer in patients who are p53 positive, phase II, EudraCT No

2005 - 2007

Comparison between Hexvix - fluorescence and whitelight cystoscopy in prospect to detection and recurrence rates in papillary urothelial tumors, phase III, EudraCT No 2011-004269-34

2007 - 2008

Gemcitabine plus Cisplatin in with or without Sorafenib sequentially versus concomitant in advanced or metastasized urothelial cancer, phase II, EudraCT No

2007 - 2009

Extended versus restricted pelvine lymphadenectomy along with cystectomy in urothelial cancer, LEA, phase III

2010 - 2011

Secondlinetherapy with TKI258 in patients with urothelial chemotherapy having progressed after firstline chemotherapy, phase II, EudraCT No 2008-005870-11

2012 - 2013

Adjuvant treatment with rec-MGAE - A3 + ASCI versus placebo in patients with advanced, non-metastatic urothelial cancer, phase II, EudraCT No 2010-024355-85

2015

Adjuvant PD-L1-selected high-risk muscle invasive bladder cancer after cystectomy, phase II, WO29636

2015

Nivolumab in 2nd line metastatic urothelial cancer patients having progressed after use of platinum agent, CA209-275, phase II

2020-

An Open-label Multi-cohort Phase 1b/2 Study of Derazantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations, Phase 1b/2, EudraCT: 2019-000359-15

2021- A Randomized Open-Label Phase III Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Subjects With Metastatic or Locally Advanced Unresectable Urothelial Cancer (TROPiCS-04) (EudraCT 2020-002964-29)

Superficial Bladder Cancer

2005 - 2007

Comparison between Hexvix - fluorescence and whitelight cystoscopy in prospect to detection and recurrence rates in papillary urothelial tumors, phase III, EudraCT No 2011-004269-34

2011 - 2012

Hexvix controlled cystoscopy in the follow up of superficial urothelial cancer in intermediate risk patients versus intravesical maintenance therapy with Mitomycin, phase II

2020-

Study of Sasanlimab (PF-06801591) in Combination With Bacillus Calmette-Guerin (BCG) in Participants With High-Risk Non-Muscle Invasive Bladder Cancer (CREST). Phase 3, EudraCT: 2019-003375-19

2021-

A Randomized Phase 2 Study of Erdafitinib Versus Investigator Choice of Intravesical Chemotherapy in Subjects Who Received Bacillus Calmette-Guérin (BCG) and Recurred With High Risk Non-Muscle-Invasive Bladder Cancer (NMIBC) and FGFR Mutations or Fusions, Phase II, EudraCT 2019-002449-39

2021- Phase 2b Clinical Study Evaluating Efficacy and Safety of TAR-200 in Combination With Cetrelimab, TAR-200 Alone, or Cetrelimab Alone in Participants With High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Intravesical Bacillus Calmette-Guerin (BCG) Who Are Ineligible for or Elected Not to Undergo Radical Cystectomy (EudraCT 2020-002646-16)

Renal Cell Carcinoma

2005 - 2013

Adjuvant vaccination therapy in M0 patients with advanced renal cell carcinoma, phase I - II

2005 - 2007

Safety of Zometa in patients with renal cell carcinoma and bone metastases, phase II

2006 - 2007

PEG-PGA and DON in advanced renal cell carcinoma, phase I

2007 - 2008

Safety and efficacy of vaccination therapy with IMA901 in patients with advanced renal cell carcinoma, phase I, EudraCT No 2005-001778-28

2008 - 2009

Safety and efficacy of vaccination therapy with IMA901 in patients with metastasized renal cell carcinoma, phase II, EudraCT No 2006-006370-25

2008 - 2009

Extended access program RAD001,

2009 - 2012

Adjuvant treatment with Sutent versus placebo in advanced renal cell carcinoma, phase II

2009 - 2010

Treatment with Axitinib and dose escalation in metastatic renal cell carcinoma, phase II

2009 - 2011

Treatment with BEV + RAD versus BEV + IFN in metastatic renal cell carcinoma, phase II, EudraCT No 2007-005460-28

2010 - 2013

Adjuvant treatment with Pazopanib versus placebo in advanced renal cell carcinoma, phase II, EudraCT No 2010-020965-26

2011 - 2012

Treatment with Sutent in combination with IMA902 in HLA-A2 positive patients in metastatic renal cell carcinoma, phase III, EudraCT No 2010-022459-45

2012 - 2014

Open-label study evaluating the sequential therapy with sorafenib followed by Pazopanib versus Pazopanib followed by Sorafenib, phase III. EudraCT No 2011-004396-36

2012 – 2014

Open randomized trial evaluating the sequential therapy with Bevacizumab, RAD001 and a tyrosine kinase inhibitor in first line clear cell metastatic renal cell carcinoma, phase II, EudraCT No 2011-005939-78

2012 – 2014

Second to fourth line therapy in metastatic renal cell carcinoma with PD-1 antibody versus Everolimus at progression after first line tyrosine kinase inhibitor therapy, phase II, EudraCT No 2011-005132-26

Testes Cancer

2007 - 2009

Darbepoietin alfa as supportive therapy in the treatment of "good / intermediate prognosis" germ cell tumors, phase II

2007 - 2012

Comparison between 1 versus 2 cycles of PEB in high-risk non seminoma germ cell tumors, phase II

Erectile Dysfunction

2007 - 2008

Vardenafil per need or daily versus placebo in patients with milde erectile dysfunction, phase II, EudraCT No 2005-001678-28

Incontinence

2005 - 2006

Safety and efficacy of Duloxetine in patients with stress incontinence, phase II

2005 - 2006

Safety and efficacy of Trospiumchlorid in patients with urge incontinence, phase II

2007 - 2009

Safety and efficacy of Botox in patients with idiopathic urge incontinence, phase II, EudraCT No 2005-001936-59

2007 - 2009

Safety and efficacy of Botox in patients with neurogenic urge incontinence, phase II, EudraCT No 2006-002143-83

2010 - 2013

Safety and efficacy of Botox in patients with idiopathic urge incontinence, phase III

2010 - 2013

Urethral sphincter system in patients with grade III stress incontinence after radical prostatectomy or TUR-P, phase II

2011

Treatment with autologous satellite cells derived from skeletal muscle in female patients with moderate urinary stress incontinence, phase II, EudraCT No 2009-011797-15

Urinary markers

2006 - 2007

Evaluation of PCA3 in exprimate urine prior to rebiopsy of the prostate

2007 - 2008

Evaluation of Annexin A3 in exprimate urine prior to rebiopsy of the prostate

Solid Tumors

2007

Treatment with Gimimatecan after firstline chemotherapy in solide tumors, phase I, EudraCT No 2005-004923-20

Clinical MPG - Studies as National lead investigators since 2003

Since 2022:

Performance of VENTANA PTEN (SP218) RxDx Assay Using OptiView DAB IHC Detection on the BenchMark ULTRA Instrument for Determining the PTEN Status of Specimens Screened for AstraZeneca Phase III Study of Capivasertib + Abiraterone Treatment for De Novo Metastatic Hormone-Sensitive Prostate Cancer (mHSPC) D361BC00001 (CAPItello-281)

Clinical MPG - Studies as Subinvestigator since 2003

2009-2013: Prostate histoscanning for the non-invasive detection and staging of prostate cancer and characterization of prostate tissues. PHS-02. NCT01191931, **168/2008MPG2**

2009 – 2013

Clinical Feasibility Investigation of the Safety and PeRformancE of GT UroLogical, LLC's Tape Mechanical OcclusivE Device (TMOD) Artificial Urinary Sphincter (RELIEF I Trial). Protocol No. TP09-045, **329/2009MPG2**

2014-2016

An open label randomized phase II trial of RNActive® cancer vaccine (CV9104) in high risk and intermediate risk patients with prostate cancer. EudraCT 2013-004489-32, **659/2013MPG1**

2009-2012

A multi-center, randomized, cross-over study to demonstrate the efficacy of pudendal neuromodulation for the treatment of neurogenic overactive bladder (Acceptance). NCT01023269, **329/2009MPG2**